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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,232	04/26/2006	Christina Mertens	I-2003.019 US	4106
24247	7590	12/16/2009	EXAMINER	
TRASKBRITT, P.C.			PESELEV, ELLI	
P.O. BOX 2550				
SALT LAKE CITY, UT 84110				
			ART UNIT	PAPER NUMBER
			1623	
			NOTIFICATION DATE	DELIVERY MODE
			12/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No. 10/577,232	Applicant(s) MERTENS ET AL.	
	Examiner Elli Pesellev	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6,8-11 and 22-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6,8-11 and 22-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/8/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 8, 2009 has been entered.

Claims 1, 5, 6, 8-11, 22-24 and 29-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

The method claims read on controlling an ectoparasitic infestation. On page 5 of the specification, lines 2-3, said terminology is defined as referring to preventing, minimizing or eliminating an infestation by ectoparasites. The term "preventing" encompasses administering the claimed formulation to healthy animals and preventing said animals from ever getting an ectoparasitic infestation. The term "eliminating" reads on 100% elimination of an actoparasitic infestation.

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(B) The state of the prior art.

Prevention and 100% elimination of an ectoparasitic infestation in animals is not known in the prior art.

(C) The amount of direction provided by the inventor.

The evidence directing to the minimizing of an ectoparasitic infestation is clearly not commensurate with the full scope of the claimed invention.

(D) The existence of working examples.

The working examples are limited to minimizing of an ectoparasitic infestation.

Claims 1, 5, 6, 8-11 and 22-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology "5-chloro-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-(4,5-dicyano-1H-imidazol-2-yl)-3-methyl-1-H pyrazole" and "at a spinosyn dosage of less than equal to about 30 mg/kg, the formulation is capable of achieving an efficacy of at least 90% in controlling flea and tick infestations in an animal for at least 7 days after the administration of the formulation" is not disclosed in the specification as originally filed.

Applicant's arguments filed September 8, 2009 have been fully considered but they are not persuasive.

Note that on page 3 of the specification, lines 39-40, the specific compound disclosed is a 3-isopropyl-1H-pyrazole derivative and not a 3-methyl-1-H-pyrazole derivative as claimed.

Applicant contends that the specification is not limited to compound 22c. This argument has not been found persuasive since the specification fails to disclose the specific compound encompassed by the present claims. The specification also fails to disclose the claimed efficacy for any compound.

Claims 1, 5, 6, 8-11 and 22-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis in the preamble of claim 1 which reads on spinosad for the terminology "at a spinosyl dosage" in the same claim.

The term "comprises" (claims 26 and 27) renders the claims indefinite since said term refers to specific compound i.e. the meets and bounds of the claimed invention cannot be determined.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25, 26, 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over the European Patent No. 0 412 849 A in combination with the International Patent No. WO 01/11963 A1.

The European Patent discloses compound discloses azole pesticides. The International Patent discloses spinosyn pesticides. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose...(T)he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerhoven* 626 F.2d 846, 850, 205 USPQ 1069, 1072 ((CCPA).

Applicant's arguments filed September 8, 2009 have been fully considered but they are not persuasive.

Applicant contends that the claimed combination is not obvious because the combination achieves unexpected results. This argument has not been persuasive because the data in the specification is limited to a single azole compound and a single spinosyn compound in specific ratios. The data presented is clearly not commensurate with the full scope of the claimed invention. Further note that the data presented fails to

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disclose the efficacy of administering compound 22c alone. Therefore, the unexpected result achieved by the combination cannot be properly evaluated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623

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